

**THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

AMGEN INC., et al.,

Plaintiffs,

v.

SAMSUNG BIOEPIS CO., LTD., et al.,

Defendants.

Civil No. 24-8417 (CPO/EAP)

MEMORANDUM ORDER

This matter having come before the Court on non-parties Celltrion, Inc. and Celltrion USA, Inc.’s (collectively, “Celltrion”) letter motion for a protective order (“Celltrion Mot.”),¹ ECF No. 157; and Defendant Samsung Bioepis (“Samsung”) having filed opposition (“Samsung Resp.”), ECF No. 162; and Celltrion having filed a reply brief, ECF No. 168, and the Court having considered the parties’ submissions; and for the reasons set forth below; and for good cause shown, the Court finds the following:

Factual and Procedural Background

1. Non-party Celltrion possesses an FDA-approved biosimilar for Amgen’s denosumab product. Following litigation brought by Amgen in *Amgen Inc. v. Celltrion, Inc.*, Civ. A. No. 24-6497 (D.N.J.) (the “*Celltrion* Litigation”), Celltrion negotiated a launch date for its denosumab biosimilars of no later than June 1, 2025. Celltrion Mot. at 2.

¹ As the parties’ letters contain extensive briefing on these issues, the Court construes the letters as motion papers.

2. The current litigation involves an infringement action by Amgen against Samsung with respect to Samsung's application for FDA approval of its denosumab biosimilar (the "*Samsung* Litigation"). See ECF No. 1, Complaint. On November 12, 2024, Amgen's counsel sent Celltrion's counsel a letter indicating that, pursuant to Paragraphs 50 and 53 of the Stipulated Confidentiality Order in the *Celltrion* Litigation, ECF No. 69, Samsung had served discovery requests on Amgen seeking production of Celltrion's confidential materials from the *Celltrion* Litigation. Celltrion Mot., Ex. B (Nov. 12, 2024 Letter from Hatcher to Cerwinski). On December 5, 2024, Samsung emailed Celltrion's counsel clarifying that it was seeking only two categories of Celltrion's confidential information: (a) "Infringement and invalidity contentions, including responses thereto and all exhibits"; and (b) "Executed settlement/license agreements between Celltrion and Amgen that would authorize the manufacture, distribution, or sale of a denosumab drug product within the United States." Celltrion Mot., Ex. C (Dec. 5, 2024 Email from Baton to Richter and Cottler).

3. On February 3, 2025, Celltrion filed its first request for leave to file a motion for a protective order, ECF No. 111, but that request was mooted by Samsung's withdrawal of its discovery requests. See ECF Nos. 124, 125.

4. Following transfer of this case into a Multi-District Litigation ("MDL") action under MDL No. 25-3138, see 25-MDL-3138, ECF No. 4, the Court stayed proceedings pending the initial case management conference. See ECF No. 147.

5. In early March 2025, Samsung narrowed its requests for Celltrion's documents. Primarily, it limited its request for Celltrion's infringement and invalidity contentions to those patents that overlapped both the Celltrion and Samsung matters. Celltrion Mot., Ex. D at 10 (March 7, 2025 Email from Speckhard to Celltrion Counsel). Moreover, Samsung requested the

Celltrion/Amgen settlement agreement in redacted form containing only “terms relating to (1) exceptions to Celltrion’s consent injunction concerning permitted pre-launch activities, and (2) the royalty rates and terms for any licensing agreements (to the extent such terms exist).” *Id.* Finally, Samsung indicated that it would “accept production of Celltrion information on an outside-counsel-eyes only basis.” *Id.*

6. Following the Case Management Conference on April 1, 2025, *see* MDL No. 25-3138, ECF No. 16, Samsung renewed its requests for Celltrion’s invalidity and infringement contentions but indicated that it was not seeking discovery concerning the settlement in the Celltrion litigation. Celltrion Mot., Ex D at 1 (April 4, 2025 Email from Speckhard to Cottler) and 5-6 (April 1, 2025 email from Speckhard to Cottler). Celltrion, in turn, agreed to allow production of Celltrion’s invalidity contentions and Amgen’s validity contentions after Celltrion had an opportunity to redact confidential information about Celltrion’s product or manufacturing process. Celltrion Mot., Ex. D at 1-2 (April 4, 2025 Email from Cottler to Speckhard). Celltrion, however, has maintained its objection to the production of the infringement and non-infringement contentions.

7. On April 8, 2025, Celltrion filed the current request for leave to file a motion for protective order. ECF No. 157. Samsung filed opposition on April 15, 2025, ECF No. 162, and Celltrion filed a reply brief on April 21, 2025, ECF No. 168. This dispute is now ripe for resolution.

Discussion

8. Federal Rule of Civil Procedure 45 establishes the rules for subpoenas served upon individuals and entities who are not parties to the underlying lawsuit. If a non-party receives a subpoena to which it objects, it can file a motion to quash or modify the subpoena, Fed. R. Civ. P.

45(d)(3), object to the production of documents by opposing a motion to compel, Fed. R. Civ. P. 45(d)(2)(B), or seek a protective order, Fed. R. Civ. P. 26(c).

9. Celltrion moves for a protective order pursuant to Rule 26(c), which provides in relevant part that, “[a] party or any person from whom discovery is sought may move for a protective order in the court where the action is pending” Fed. R. Civ. P. 26(c)(1). “The court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including . . . : (G) requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way[.]” Fed. R. Civ. P. 26(c)(1)(G).

10. “The party seeking a protective order ‘over discovery material must demonstrate that “good cause” exists for the order[.]’” which means that ““disclosure will work a clearly defined and serious injury to the party seeking closure.”” *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 671 (3d Cir. 2019) (quoting *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (further quotations omitted)). ““The injury must be shown with specificity.”” *Avandia*, 924 F.3d at 671 (quoting *Pansy*, 23 F.3d at 786). “Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning, do not support a good cause showing.” *Pansy*, 23 F.3d at 786 (cleaned up).

11. The Third Circuit Court of Appeals has set forth a non-mandatory, non-exhaustive list of factors that courts may consider in determining whether good cause exists for the grant of a protective order, including:

1. whether disclosure will violate any privacy interests;
2. whether the information is being sought for a legitimate purpose or for an improper purpose;
3. whether disclosure of the information will cause a party embarrassment;

4. whether confidentiality is being sought over information important to public health and safety;
5. whether the sharing of information among litigants will promote fairness and efficiency;
6. whether a party benefitting from the order of confidentiality is a public entity or official; and
7. whether the case involves issues important to the public.

Avandia, 924 F.3d at 671 (footnote omitted). Ultimately, the trial court “is best situated to determine what factors are relevant to any given dispute,” but “[t]he Court’s analysis . . . should always reflect a balancing of private versus public interests.” *Id.* at 671-72 (cleaned up).

12. Guided by the foregoing principles, the Court finds that Celltrion has established its entitlement to a protective order.

13. First, the requested information seeks the infringement and non-infringement contentions in the *Celltrion* Litigation, and the “thousands of pages of Celltrion internal documents cited therein, [which] relate solely to Celltrion’s highly technical and confidential process for manufacturing denosumab.” Celltrion Mot. at 4. Repeatedly, during the *Celltrion* Litigation, this Court recognized that, given the risk of harm to Celltrion, its trade secrets and confidential information regarding its biosimilar constituted protected information that warranted orders sealing it from public access. *See* Civ. A. No. 24-6497, ECF No. 111, 124, 159, 193, 212, 243, 272, 354, 362, 367, 374 (Orders). Samsung does not dispute the confidential nature of this information. *See generally* Samsung Resp.

14. Second, Celltrion has identified a clearly-defined and serious injury that would result from disclosure of its information. “Serious injury includes the revelation of sensitive business information that competitors could use to a party’s competitive disadvantage.” *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, No. 10-6108, 2017 WL 11633521, at *2 (D.N.J. Feb. 23. 2017) (citing *Leap Sys. v. Moneytrax, Inc.*, 638 F.3d 216, 219 (3d Cir. 2011)). “Good cause justifies the sealing of information where the need to protect ‘the parties’ confidential proprietary business and

competitive interests’ is present.” *Id.* (quoting *Mylan Inc. v. SmithKline Beecham Corp.*, 723 F.3d 413, 423 n.3 (3d Cir. 2013) (emphasis in original)). Courts routinely find good cause to protect the confidentiality of the type of information at issue here. *See, e.g., Morgan v. Quest Diagnostic Inc.*, No. 20-430, 2024 WL 4025567, at *3 (D.N.J. Apr. 23, 2024) (finding that good cause exists to grant a protective order where a non-party claims a privacy or other confidentiality interest); *Teva Pharms. USA, Inc. v. Sandoz Inc.*, No. 17-275, 2017 WL 11512167, at *2 (D.N.J. May 2, 2017) (“Disclosure of the information sought to be sealed could cause significant competitive harm because disclosure of the information would provide public insight into the private business and commercial operations of Defendant giving competitors an unfair advantage in a highly competitive marketplace.”); *Jon Feingersh Photography, Inc. v. Pearson Educ., Inc.*, No. 11-5122, 2012 WL 957534, at *2-3 (E.D. Pa. Mar. 13, 2012) (granting motion for protective order covering non-public financial data, as well as sales and marketing projections and forecasts, which if released, would put the defendant at a competitive disadvantage); *Goldenberg v. Indel, Inc.*, No. 09-52-2, 2012 WL 15909, at *3-4 (D.N.J. Jan. 3, 2012) (recognizing that “the confidentiality of business agreements, trade secrets or commercial information are a legitimate private interest and the disclosure of this information can be used for the improper purpose of causing harm to the litigant’s competitive standing in the marketplace.” (citations omitted)); *Sprinturf, Inc. v. Sw. Recreational Indus., Inc.*, 216 F.R.D. 320, 324 (E.D. Pa. 2003) (concluding that “past and future market share, the size of future markets, . . . and proprietary information regarding the development of . . . [a] product line” constitutes confidential commercial information, the disclosure of which could result in competitive disadvantage).

15. Here, Celltrion asserts that it has settled its litigation with Amgen to launch its denosumab biosimilar beginning on June 1, 2025. Celltrion Mot. at 1. Samsung, a direct

competitor of Celltrion, “presumably intends to launch its FDA-approved, denosumab biosimilar around the same time.” *Id.* (footnote omitted). Celltrion contends that it will face “substantial competitive harm” if Samsung is permitted to access this “extremely sensitive, unredacted information” by giving Samsung access to Celltrion’s technical information *Id.* at 2. Given that Celltrion stands to face financial harm and loss of competitive advantage from disclosure of this information to Samsung, it has adequately established “good cause” for a protective order.²

16. Third, the public right to access does not outweigh Celltrion’s interest in protecting its confidential information. “One well-settled exception to the right of access is the protection of a party’s interest in confidential commercial information, such as a trade secret, where there is a sufficient threat of irreparable harm.” *Supernus Pharms., Inc. v. TWi Pharms., Inc.*, No. 15-369, 2019 WL 13043558, at *2 (D.N.J. July 17, 2019) (cleaned up); *see also Jazz Pharms*, 2017 WL 11633521, at *2 (“The public’s right of access to court submissions is more restrictive when a party seeks the protection of a party’s interest in confidential commercial information where there is a sufficient threat of irreparable harm.” (citing *Pansy*, 23 F.3d at 786-91)). “The presence of such confidential information weighs against public access and therefore, documents containing such information may be protected from disclosure” *Jazz Pharms*, 2017 WL 11633525, at *2 (citing *Pansy*, 23 F.3d at 786-91); *see also In re Gabapentin Litig.*, 312 F. Supp. 2d 653, 664

² Samsung argues that Celltrion fails to set forth a clearly defined and serious injury that would result. Samsung Resp. at 3-4 (citing *Wyeth v. Organon Pharma Inc.*, No. 09-3235, 2010 WL 4117157, at *4 (D.N.J. Oct. 19, 2010)). In *Wyeth*, the defendants in a patent infringement suit sought to compel the plaintiff to produce certain license agreements and settlement agreements with third parties. *Id.* at *1. The plaintiff objected on grounds of irrelevancy and that third parties maintained a confidentiality interest in the settlement-related agreements. *Id.* The court found that the license agreements were discoverable and that the plaintiff’s third-party confidentiality concerns did not outweigh the legitimate bases for production. *Id.* at *4. By contrast here, the third party itself is seeking a protective order based on its desire to protect disclosure of confidential, technical information to a direct competitor. Accordingly, the Court does not find *Wyeth* persuasive here.

(D.N.J. 2004) (holding that courts can deny access to judicial records where they are sources of business information that might harm a litigant’s competitive standing) (quotations omitted). “In addition, ‘if a case involves private litigants, and concerns matters of little legitimate public interest, that should be a factor weighing in favor of granting or maintaining an order of confidentiality.’” *Supernus Pharms.*, 2019 WL 13043558, at *2 (quoting *Pansy*, 23 F.3d at 788).

17. The litigation at issue involves private parties in a private patent infringement suit. Beyond the generalized public interest in access to judicial proceedings, this matter does not implicate any particular public concern. Moreover, Samsung seeks disclosure of Celltrion’s information not for public use but rather for itself, to defend against Amgen’s allegations. Accordingly, no defined public interest exists that outweighs Celltrion’s interest in protecting its confidential information.

18. Fourth, Samsung has not established that the information is being sought for a proper purpose. “[A] party seeking discovery from a third party is required to show the relevance and need of the discovery sought.” *Avago Techs. U.S., Inc. v. IPtronics Inc.*, 309 F.R.D. 294, 299 (E.D. Pa. 2015) (citation omitted). “[T]he standards for nonparty discovery require a stronger showing of relevance than for simple party discovery.” *Stamy v. Packer*, 138 F.R.D. 412, 419 (D.N.J. 1990) (citations omitted).

19. In opposing the motion for protective order, Samsung claims that some of the patents currently in suit in the *Samsung* Litigation were also at issue in the *Celltrion* litigation. Samsung Resp. at 4. According to Samsung, the requested discovery will “reveal Amgen’s own view of claim scope.” *Id.* More specifically, “these documents will show whether Amgen has inconsistently interpreted the claims for purposes of infringement and validity across the *Celltrion* litigation and the present case.” *Id.* Samsung claims that it is entitled to know whether Amgen

characterized the scope of the claims in a way that contradicts Amgen's infringement contentions or supports Samsung's invalidity defenses. *Id.* (citing *Data Engine Techs. LLC v. Google LLC*, 10 F.4th 1375, 1381 (Fed. Cir. 2021)).

20. The Court rejects Samsung's arguments on three grounds. Primarily, Samsung has put forth no basis for its belief that Amgen has taken inconsistent positions on the scope of its patents between the *Samsung* and the *Celltrion* Litigations. "The discovery rules are designed to assist a party to prove a claim it reasonably believes to be viable *without discovery*, not to find out if it has any basis for a claim." *Micro Motion, Inc. v. Kane Steel Co.*, 894 F.2d 1318, 1327 (Fed. Cir. 1990) (emphasis in original). Moreover, even had Amgen made inconsistent representations about the scope of its claims, for judicial estoppel to apply, the party seeking to assert an inconsistent position "must have succeeded in persuading a court to adopt the earlier position, thereby posing a risk of inconsistent court determinations." *Transclean Corp. v. Jiffy Lube Int'l, Inc.*, 474 F.3d 1298, 1307 (Fed. Cir. 2007) (cleaned up). The Court never made any claim construction rulings in the *Celltrion* Litigation. As such, Amgen's prior representations would not bar different claim construction positions here.³ Finally, Amgen's infringement allegations and Celltrion's non-infringement allegations in the *Celltrion* Litigation rest heavily on Celltrion's

³ Samsung's case citations in support are inapposite. *See* Samsung Resp. at 4. In *Data Engine Technologies, LLC v. Google LLC*, 10 F.4th 1375 (Fed. Cir. 2021), the court was tasked with construing the claims and noted that plaintiff—in the same litigation—could not insist on one construction to avoid invalidity and on another construction to find infringement. *Id.* at 1381. Likewise, in *TVIM, LLC v. McAfee, Inc.*, 851 F.3d 1356 (Fed. Cir. 2017), the court stated generally that "[c]laim terms must be construed the same way for the purpose of determining invalidity and infringement." *Id.* at 1362 (citation omitted).

By contrast here, Samsung seeks to compare Amgen's infringement contentions and Celltrion's non-infringement contentions in the *Celltrion* Litigation with Amgen's infringement contentions and Samsung's non-infringement contentions in the *Samsung* Litigation. Samsung cites no case law suggesting that a patent holder cannot take inconsistent positions in different litigations, particularly when different accused products are at issue.

products and manufacturing processes, which would not be probative of whether Samsung's products and processes infringe. As noted by Celltrion, Samsung's requests appear to be "a veiled attempt to piggyback off Celltrion and its counsel's work to obtain a strategic advantage in the denosumab biosimilar market." Celltrion Mot. at 4.

21. Finally, no less restrictive means are adequate to protect Celltrion's interest. Samsung claims that it seeks production of Celltrion's information on an "Outside Attorneys' Eyes Only" basis, thus avoiding the speculated harm. Samsung Resp. at 3. Given that Amgen, Celltrion, and Samsung are all direct competitors, however, "[i]t would be divorced from reality to believe that either party here would serve as the champion of its competitor . . . either to maintain the confidentiality designation or to limit public disclosure as much as possible during trial." *Micro Motion, Inc.*, 894 F.2d at 1325. Indeed, "[Celltrion] would, in fact, lose all control of the situation since disclosure of its information depends on the action by a court before whom it has no standing." (citation omitted). *Id.*⁴

22. Moreover, even if such restrictions would be adequate to protect Celltrion, "a protective order which limits to whom information may be disclosed does not eliminate the requirements of relevance and need for information." *Id.* "Rule 26(g) requires a party to make a 'reasonable inquiry' before seeking discovery[.]" *Id.* at 1327. Given Samsung's failure to establish either relevance or need, the mere existence of confidentiality provisions does not entitle Celltrion to obtain proprietary information from a third party.⁵

⁴ Samsung cites a case from the District of Minnesota to substantiate its position that designation of information as "attorneys' eyes only" alleviates concerns about disclosure of confidential information to a competitor. Samsung Resp. at 3 (citing *Datcard Sys., Inc. v. PacsGear, Inc.*, No. 11-mc-25, 2011 WL 2491366, at *2 (D. Minn. June 23, 2011)). That case, however, involved an ancillary matter in which the court provided little analysis into the potential competitive harm faced by the objecting third-party. *Id.* at *1-2.

⁵ As an alternative proposal, Celltrion argues that to the extent the contentions are

THEREFORE, it is this **24th** day of **April 2025**;

ORDERED that Celltrion Motion for Protective Order is **GRANTED**; and

IT IS FURTHER ORDERED that Amgen is barred from producing the infringement and non-infringement contentions from the *Celltrion* Litigation to Samsung.

s/Elizabeth A. Pascal
ELIZABETH A. PASCAL
United States Magistrate Judge

cc: Christine P. O'Hearn, U.S.D.J.

probative, Samsung should only be permitted access after Amgen has served all of its contentions in the *Samsung* case and the parties begin exchanging claim construction positions. That proposal would give the parties a chance to discuss settlement, thus “obviating Samsung’s need to access Celltrion’s highly confidential information and avoiding the harm to Celltrion.” Celltrion Reply at 2. The Court need not consider the propriety of this proposal because Samsung has failed to establish legitimate grounds to compel production of Celltrion’s infringement contentions.